REMARKS

Reconsideration and withdrawal of the objections to and the rejections of this application are respectfully requested.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 7-9 and 14-16 are under examination in this application. Claims 1 and 9 are currently amended.

Support for the amended claims can be found throughout the application. Specifically, support for the amendments to claims 1 and 9 can be found in the paragraph beginning on page 9, line 28, of the specification. Support for the previous amendment to claim 14 (in the Amendment filed on April 21, 2003) can be found in the paragraph beginning on page 8, line 13. Support for the recitation "tolerance attenuating" in claims 15 and 16 can be found on page 7, line 31. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTION UNDER 35 U.S.C. §112, 1ST PARAGRAPH, IS OVERCOME

Claims 9-12 and 14 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Claims 10-12 have been cancelled; the rejection with respect to claims 9 and 14 is traversed.

The Examiner is thanked for acknowledging that the specification is enabling for a tolerance-attenuating dose of an NMDA receptor antagonist. As currently presented, claim 9 recites a tolerance-attenuating dose of ketamine, obviating its rejection and that of depended claim 14 under 35 U.S.C. §112, first paragraph. Therefore, reconsideration and withdrawal of this rejection are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH, ARE OVERCOME

Claims 1-3, 5-8, 11-12 and 14 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed.

(i) Claim 11 has been cancelled and claim 1 does not recite "derivative".

(ii) Claims 6 and 10 have been cancelled.

(iii) Claim 14 has been amended to clarify what percent weight of ketamine is being claimed.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, are respectfully requested.

IV. THE REJECTION UNDER 35 U.S.C. §102 IS OVERCOME

Claims 1-3, 6, 9-12 and 15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Gervitz *et al.* (5,635,204). The rejection with respect to pending claims 1, 9 and 15 is traversed.

Gervitz *et al.* involves a method of inducing surgical anesthesia in a mamal by transdermally administering via a transdermal patch an amount of an amnesia producing drug (ketamine), and after an amnesic state is produced, transdermally administering amounts of clonidine and fentanyl which are sufficient to produce surgical anesthesia. The method of inducing surgical anesthesia taught by Gervitz *et al.* necessarily results in the amnesia inducing use of ketamine, whereby ketamine attains "plasma level concentrations of 100-150 ng/ml", and the method of Gervitz *et al.* necessarily involves systemic or central administration. (5,635,204, Col. 2, Ln. 66-67).

Claims 1, 9 and 15 provide a topical pharmaceutical composition comprising ketamine and morphine, and methods for peripheral analgesia using the topical pharmaceutical composition. Simply, in contrast to the instant invention, Gervitz *et al.* provides "transdermal administration" that is "a general anesthetic" which results in "profound sedation." In the present claim recitations: Claim 1 recites that delivery is "not to central opiate receptors," Claim 9 recites that the method is "not central systemic analgesia ... and not centrally or systemically, analgesic dose," and Claim 16 recites "a tolerance attenuating, peripherally but not centrally or systemically analgesic dose." Gervitz *et al.* is clearly contrary to, and teaches away from, and fails to teach or suggest, the recitations of the instant claims.

The method of Gervitz *et al.* is not a single prior art reference that discloses each and every element of the presently claimed invention. The method of the present invention provides for peripheral analgesia, not systemic or central, and is therefore not previously taught or suggested by Gervitz *et al.*

Accordingly, Gervitz *et al.* fails to teach the instant invention. Reconsideration and withdrawal of the §102(b) rejections are requested.

V. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

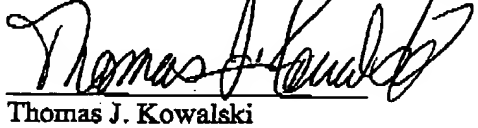
Claims 5 and 14 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gervitz *et al.*, as applied to claims 1-3, 6, 9-12 and 15 under 35 U.S.C. §102(b) above, and further in view of Nelson *et al.* (5,840,731) and Needham *et al.* (6,261,582). Claims 7-8 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gervitz *et al.*, as applied to claims 1-3, 6, 9-12 and 15 under 35 U.S.C. §102(b) above, and further in view of Kaneko *et al.* (Anethesiology '94). Claim 16 was rejected under 35 U.S.C. §103(a) as being unpatentable over Gervitz *et al.* in view of Smith *et al.* (6,194,000). These rejections will be addressed collectively, and are traversed.

Initially, as to all of the §103 rejections, reference is made to the forgoing distinctions between Gervitz *et al.* and the instant invention. Further, as was discussed in detail in the Amendment filed on April 21, 2003, no combination of Gervitz *et al.* and any of the other cited references teaches or suggests the claimed invention. Reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are requested.

CONCLUSION

In view of the Amendment filed on April 21, 2003 and the amendments and remarks herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application, reconsideration, and withdrawal of the objections and rejections, and prompt issuance of a Notice of Allowance are respectfully requested.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

Thomas J. Kowalski
Reg. No. 32,147
(212) 588-0800

EV 196783239 US

EXPRESS MAIL
UNITED STATES POSTAL SERVICE®

Customer Copy
Label 11-F June 2002

Post Office To Addressee

ORIGIN (POSTAL USE ONLY)

PO ZIP Code: 10022
Day of Delivery: ☐ Next ☒ Second
Flat Rate Envelope: ☐
Date In: Mo. 4 Day 21 Year 03
☐ 12 Noon ☐ 3 PM
Postage: $ 17.85
Time In: 10:58 ☐ AM ☐ PM
Military: ☐ 2nd Day ☐ 3rd Day
Return Receipt Fee
Weight: lbs. 8 ozs. 1
Int'l Alpha Country Code
COD Fee
Insurance Fee
No Delivery: ☐ Weekend ☐ Holiday
Acceptance Clerk Initials: LMA
Total Postage & Fees: $ 17.85

DELIVERY (POSTAL USE ONLY)

Delivery Attempt: Mo. Day | Time ☐ AM ☐ PM | Employee Signature
Delivery Attempt: Mo. Day | Time ☐ AM ☐ PM | Employee Signature
Delivery Date: Mo. Day | Time ☐ AM ☐ PM | Employee Signature

NEW YORK, N.Y. G.P.O. STA. APR 21 2003 USPS

CUSTOMER USE ONLY
METHOD OF PAYMENT:
Express Mail Corporate Acct. No.
Federal Agency Acct. No. or Postal Service Acct. No.

FROM: (PLEASE PRINT) PHONE 212 588 0800
Amy Leahy, Ph. D.
FROMMER LAWRENCE & HAUG, LLP
745 5TH AVE FL 10
NEW YORK NY 10151-1000

AL/im 830015-2006.2

TO: (PLEASE PRINT) PHONE
Assistant Commissioner for Patents
Box Patent Appln.
Washington, D.C. 20231

PRESS HARD.
You are making 3 copies.

FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.com

Mailed Via Exp. Mail #EV196783239US on 4/21/03

Serial No. 09/806,645 File No. 830010-2006.2 By ALJM
Title In the Matter of the Application of Kolesnikov et al.
The following due ——— in the U.S. Patent Office, was received in the Patent Office

- ☐ Affidavit ☐ Declaration
- ☒ Amendment with request for interview
- ☐ Preliminary Amendment
- ☐ Amendment After Final Rejection
- ☐ Request for Extension of Time
- ☐ Provisional Patent Application
- ☐ Application for Patent, including —— Pages Specification —— Claims
- ☐ Declaration ☐ Oath ☐ Power
- ☐ Request for Filing Continuation or Divisional Application —— sheets, in duplicate
- ☐ File Wrapper Continuation Patent Application ——— sheets, in duplicate
- ☐ PCT Request ——— sheets, including
- ☐ Transmittal Letter to the US/RO
- ☐ Assignment ☐ Recordation Cover Sheet
- ☒ Express Mail Mailing Certificate (separate sheet)
- ☐
- ☒ Check No. 026027 for $ 18.00
- ☐ Deposit Account Order Form
- ☐ Drawing —— Sheet(s)
- ☒ Information Disclosure Statement (Suppl.)
- ☒ PTO Form 1449, (1 Ref.)
- ☐ Issue Fee Transmittal
- ☐ Brief ☐ Letter
- ☐ Application for TM Registration Including ——— Specimens
- ☐ Status Request ☐ Notice of Appeal
- ☐ Petition ☐ Response
- ☐ Priority Document
- ☐ Small Entity Declaration
- ☒ Decl. of Gavril Pasternak and Yuri Kolesnikov

Mailed Via Exp. Mail #EV196783239US on 4/21/03

Serial No. 09/806,645 File No. 830010-2006.2 By ALJM
Title In the Matter of the Application of Kolesnikov et al.
The following due ——— in the U.S. Patent Office, was received in the Patent Office

- ☐ Affidavit ☐ Declaration
- ☒ Amendment with request for interview
- ☐ Preliminary Amendment
- ☐ Amendment After Final Rejection
- ☐ Request for Extension of Time
- ☐ Provisional Patent Application
- ☐ Application for Patent, including —— Pages Specification —— Claims
- ☐ Declaration ☐ Oath ☐ Power
- ☐ Request for Filing Continuation or Divisional Application —— sheets, in duplicate
- ☐ File Wrapper Continuation Patent Application ——— sheets, in duplicate
- ☐ PCT Request ——— sheets, including
- ☐ Transmittal Letter to the US/RO
- ☐ Assignment ☐ Recordation Cover Sheet
- ☒ Express Mail Mailing Certificate (separate sheet)
- ☐
- ☒ Check No. 026027 for $ 18.00
- ☐ Deposit Account Order Form
- ☐ Drawing —— Sheet(s)
- ☒ Information Disclosure Statement (Suppl.)
- ☒ PTO Form 1449, (1 Ref.)
- ☐ Issue Fee Transmittal
- ☐ Brief ☐ Letter
- ☐ Application for TM Registration Including ——— Specimens
- ☐ Status Request ☐ Notice of Appeal
- ☐ Petition ☐ Response
- ☐ Priority Document
- ☐ Small Entity Declaration
- ☒ Decl. of Gavril Pasternak and Yuri Kolesnikov